REMARKS/ARGUMENTS

Claims 1 to 19, as amended, appear in the application for the Examiner's review and consideration. Claims 1, 4, 12, and 19 have been amended to more particularly point out the claimed subject matter and to correct inadvertent minor spelling and editorial errors, but no new matter has been added. Applicants submit also a replacement paragraph for the Abstract of the Disclosure.

The Office Action objects to Applicants' Abstract of the Disclosure as allegedly failing to contain the proper content. This rejection has been rendered moot by the replacement abstract.

Claim 16 stands rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement for the reasons set forth on page 2-3 of the Office Action. Applicants respectfully traverse this rejection.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *See, e.g., Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991). As long as a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if not every nuance of the claims is explicitly described in the specification, the written description requirement is met. *In re Alton*, 76 F.3d 1168, 37 U.S.P.Q.2d 1578 (Fed. Cir. 1996). "*Ipsis verbis* disclosure is not necessary to satisfy the written description requirement." *Fujikawa v. Wattanasin*, 93 F.3d 1559, 39 U.S.P.Q.2d 1895 (Fed. Cir. 1996).

Claim 16 is adequately described, because when the skilled artisan reads the abbreviation "HPLC," he immediately recognizes that the author is referring to the commonly used chemical characterization technique "High Performance Liquid Chromatography." *See, e.g.*, John McMurry, *Organic Chemistry*, 4th Ed., p. 447 (Brooks/Cole Publishing Co. 1996). Furthermore, the phrase "HPLC relative to retention times of about 0.26, 0.34, 0.37, or 0.80" is adequately described in the specification. The specification states: "The impurities were determined by their relative retention times (RRT) as compared to azithromycin" (Specification at p. 7, ll. 3-4.) This statement makes it clear to one of skill in the pertinent art that the retention times listed are intended to be relative to retention times of azithromycin, rather than in terms of absolute time. The rejection of claim 16 under 35 U.S.C. § 112, first paragraph for failing to comply with the written description requirement, therefore, cannot stand and should be withdrawn.

Claims 4, 12, 16, and 19 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly failing to satisfy the definiteness requirement for the reasons set forth on page 3 of the Office Action. The claim amendments have rendered moot the rejection with respect to claims 4, 12, and 19. As to claim 16, applicants respectfully traverse.

In determining whether claim language satisfies the definiteness requirement, an examiner must read the language in light of (1) the disclosures of the application, (2) the prior art, and (3) the knowledge of one of ordinary skill in the pertinent art. *See Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565 (Fed. Cir. 1986); M.P.E.P. § 2173.02. As argued above, when one combines the disclosures of the specification with the knowledge of the skilled artisan, the meaning of the language used in claim 16 is clear. Thus, the rejection of claim 16 under 35 U.S.C. § 112, second paragraph, for failing to comply with the definiteness requirement cannot stand and should be withdrawn.

Claims 1-14 and 16 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. patent No. 6,764,997 to Tenegauzer *et al.* ("the '997 patent"). Applicants traverse this rejection.

In order to anticipate an invention, a single prior art reference must disclose "each and every element of the claimed invention." *Structural Rubber Products Co. v. Park Rubber Co.*, 749 F.2d 707, 715 (Fed. Cir. 1984); *See also* M.P.E.P. § 2131. The '997 patent does not disclose each and every element of the claim; and, therefore, it cannot anticipate the claims.

The '997 patent is directed to stabilized azithromycin compositions including an intimate admixture of azithromycin and a stabilizing-effective amount of an antioxidant. (The '997 patent, col. 1, ll. 61-65). The '997 patent discloses that the addition of antioxidants to azithromycin protects it from degradation at elevated temperatures. (*Id.* at col. 2, ll. 63-67). The formulation may be a unit dose packet dosage form or sachet. (*Id.* at col. 6, ll. 64-66). Tablets of the formulation were placed in aluminum laminated bags and the tablets were stored for five to seven days at 55°C. (*Id.* at col. 16, ll. 42-46). There is no data on the ability of the aluminum laminated bag to limit degradation of azithromycin upon storage with an antioxidant. (*Id.* at Table 6).

The '997 patent does not disclose a container for packaging azithromycin comprising a gas impermeable material, which can limit degradation products to no greater than 5% by weight. The '997 patent limits degradation by the use of antioxidants. Therefore, the '997

patents fails to disclose each and every limitation of the claim. The rejection of claims 1-14 and 16 under 35 U.S.C. § 102(e) as being anticipated by the '997 patent, therefore, cannot stand and should be withdrawn.

Claims 17-19 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by the '997 patent. Applicants traverse this rejection.

As discussed above regarding claims 1-14 and 16, the '997 patent does not disclose a container with a gas impermeable material which can limit degradation products to no greater than 5% by weight. Accordingly, the '997 patent cannot disclose a method of storing azithromycin using the absent container. Thus, the rejection of claims 17-19 under 35 U.S.C. § 102(e) as being anticipated by the '997 patent, therefore, cannot stand and should be withdrawn.

Claims 1-4 and 10-15 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. publication No. 2005/0051453 to Schuler *et al.* ("the '453 publication") for the reasons set forth on page 5 of the Office Action. Applicants traverse this rejection.

"Inherent anticipation requires that the missing descriptive material is necessarily present, not merely probably or possibly present, in the prior art." *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295, 63 U.S.P.Q.2d 1597 (Fed. Cir. 2002) .

The '453 publication discloses a sealing a multi-layered package by a heated roller to provide an improved pharmaceutical package. (The '453 publication, p. 1, ¶ [0006]). It was discovered that localized heating of a portion of the layers to be sealed, such as by using a roller comprising a heating element, during the sealing process, lowers the temperature of the cavity during the sealing process; thereby, the process lowers the temperature experienced by the pharmaceutical formulation within the cavity as compared to a uniform heating process. (*Id.* at p. 3, ¶ [0036]). Examples of active agents suitable for use include azithromycin among many others.

Claim 1 recites a container for packaging azithromycin which degradation products of azithromycin upon storage are limited to no more than 5% by weight of the azithromycin. The '453 publication fails to recite this limitation. In fact, the '453 publication discloses azithromycin in a laundry list of compounds without any specificity as to the product degradation limit. Thus, the '453 publication, fails to establish that the degradation limit is necessarily present, and not merely probably or possibly present in the reference. Therefore, the rejection of claims 1-4 and 10-15 under 35 U.S.C. § 102(e), cannot stand and should be withdrawn.

The Office Action objects to Claims 17-19 under 35 U.S.C. § 102(e) as allegedly being anticipated by the '453 publication for the reasons set forth on page 5 of the Office Action. Applicants traverse this rejection.

As discussed above, the '453 publication does not disclose a container with a gas impermeable material which can limit degradation products to no greater than 5% by weight. Accordingly, the '453 publication cannot disclose a method of storing azithromycin using the absent container. Therefore, the rejection of claims 17-19 under 35 U.S.C. § 102(e), cannot stand and should be withdrawn.

Claims 5-9 and 14-16 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over either the '997 patent or the '453 publication. Applicants traverse this rejection.

The Federal Circuit in *In re Dembiczak*, 175 F.3d 994 (Fed. Cir. 1999), set forth three requirements to make out a *prima facie* case of obviousness under 35 U.S.C. § 103(a) in light of the prior art. In order to be *prima facie* obvious: (i) there must be some teaching or suggestion in the prior art to modify or combine references to form the claimed invention, (ii) there must be a reasonable expectation of success taught or suggested in the prior art, and (iii) all of the elements of the claimed invention must be found in the prior art. *See also* M.P.E.P. § 2143. In order to meet his burden to show that the claims are *prima facie* obvious in light of the prior art, the Examiner must expressly point to something in the references themselves, something in the nature of the problem to be solved, or something in the general knowledge of persons reasonably skilled in the art that would constitute objective evidence of a teaching or suggestion to combine the cited references. *See In re Lee*, 277 F.3d 1338 (Fed. Cir. 2002).

As discussed above, the '997 patent does not disclose or suggest data on the stability of azithromycin stored in an aluminum laminated bag, that lacks an antioxidant. In fact, the '997 patent teaches away from the claims, because the reference teaches that stability can only be obtained by the addition of an antioxidant and that the use of aluminum laminated bags in stabilizing azithromycin would be unsuccessful.

The '453 publication merely generically mentions azithromycin in a laundry list of compounds that may be used with the invention. There is no disclosure or suggestion that the container can limit the level of degradation to no greater than 5% by weight.

Thus, the rejection of claims 5-9 and 14-16 under 35 U.S.C. § 103(a) over either the '997 patent or the '453 publication, cannot stand and should be withdrawn.

Claims 1-16 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. patent Nos. 3,331,495 to Lechzik *et al.* ("the '495 patent") in view of any one of 5,605,889 to Curatolo *et al.* ("the '889 patent"), the '997 patent, or the '453 publication for the reasons set forth on pages 6-7 of the Office Action. Applicants respectfully traverse the rejection.

The '495 patent discloses a moisture-proof push-through package for the storage of medicines that contains an aluminum foil base and outer layer. (The '495 patent, col. 1, l. 55 to col. 2 l. 11). The '889 patent discloses a single dose packet of azithromycin wherein the packet is made up of white paper/aluminum/polyethylene laminate sheets. (The '889 patent, col. 15, ll. 43-45, and col. 16, ll. 20-40). This dose packet is described as having the ability to eliminate adverse food effect when the azithromycin is ingested. (*Id.* at col. 22, l. 65 to col. 23, l. 2).

Neither the '889 patent nor the '997 patent discloses a method for limiting the degradation products of azithromycin upon storage by way of the use of a protective container. Their combination with either the '495 patent or the '142 publication, therefore, do not disclose or suggest the missing limitation of the references. As for the '453 publication, the Office Action does not point out any suggestion or motivation to combine it with either the '495 patent or the '142 publication. The rejection of claims 1-16 under 35 U.S.C. § 103(a) as obvious over the above-referenced combinations, therefore, cannot stand and should be withdrawn.

Claims 1-16 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. publication No. 2004/0104142 to Dobler *et al.* ("the '142 publication") in view of any one of the '889 patent, the '997 patent, or the '453 publication for the reasons set forth on page 6 of the Office Action. Applicants respectfully traverse the rejection.

The '142 publication discloses an aluminum blister package for the storage of topiramate tablets, which is described as affording the tablets improved stability and shelf-life. (The '142 publication, p. 1, ¶ 7).

The '142 publication, however, does not disclose or suggest either explicitly or inherently azithromycin or that the container can limit the level of degradation of azithromycin to no greater than 5% by weight. As discussed above, the secondary references fail to remedy the deficiency of the '142 publication. Therefore, the rejection of claims 1-16 under 35 U.S.C. § 103(a) over the '142 publication in view of any one of the '889 patent, the '997 patent, or the '453 publication cannot stand and should be withdrawn.

Claims 17-19 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over the '496 patent in combination with the '889 patent, the '997 patent, or the '453 publication for the reasons set forth on page 7 of the Office Action. Claims 17-19 also stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over the '142 publication in combination with the '889 patent, the '997 patent, or the '453 publication. Applicants traverse these rejections.

As discussed above, the primary references either the '496 patent or the '142 publication fails to disclose or suggest a container that can limit the level of degradation of azithromycin to no greater than 5% by weight. As discussed above, the secondary references fails to remedy this deficiency, because they too lack any disclosure or suggest of a container that can limit the level of degradation of azithromycin to no greater than 5% by weight. Furthermore, the references do not suggest the combination with another to obtain the recited claims.

Therefore, the rejection of claims 17-19 under § 103 for the reasons set forth above cannot stand and should be withdrawn.

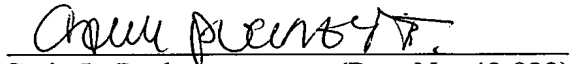
Accordingly, it is believed that claims 1-19 are now in condition for allowance, early notice of which would be appreciated.

If any outstanding issues remain, the examiner is invited to telephone the undersigned at the telephone number indicated below to discuss the same. No fee is believed to be due for the submission of this response. Should any fees be required, please charge such fees to Kenyon & Kenyon, LLP Deposit Account No. 11-0600.

Respectfully submitted,

KENYON & KENYON LLP

Dated: February 8, 2006

By: 
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